

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF PENNSYLVANIA
and STATE OF NEW JERSEY,

Plaintiffs,

v.

No. 17-CV-4540-WB

DONALD J. TRUMP, *in his official capacity as President of the United States*; ALEX M. AZAR II, *in his official capacity as Secretary of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEVEN T. MNUCHIN, *in his official capacity as Secretary of the Treasury*; UNITED STATES DEPARTMENT OF THE TREASURY; RENE ALEXANDER ACOSTA, *in his official capacity as Secretary of Labor*; and UNITED STATES DEPARTMENT OF LABOR,

Defendants,

LITTLE SISTERS OF THE POOR SAINTS
PETER AND PAUL HOME,

Intervenor-Defendant.

**REPLY IN SUPPORT OF INTERVENOR-DEFENDANT'S
MOTION FOR SUMMARY JUDGMENT**

INTRODUCTION

The States’ brief fails to answer the central argument presented by the Little Sisters. The Little Sisters established that the Final Rules are required by RFRA because the so-called “accommodation” actually uses the religious employer’s health plan to provide the objected-to coverage. Br. 20-23. That coverage is “part of the same plan” provided by the employer, with the employer executing “an instrument under which the plan is operated,” so that employees do *not* have to have two plans. Br. 21-22 (citations omitted). Once those facts are understood, *Hobby Lobby’s* substantial burden analysis controls, and RFRA requires the Final Rules. Br. 24-26.

The States quibble about whether the federal government conceded facts about the Mandate’s operation at the *Zubik* oral argument or in supplemental briefing (answer: both), but nowhere do they actually argue that these concessions are *wrong*. Nor do they dispute that the actions required by the Mandate would force the Little Sisters to violate their religious beliefs. *See* States’ Response to Statement of Undisputed Facts, Dkt. 224-1 ¶ 56. These failures are dispositive, and show why the Final Rule is necessary to comply with RFRA. The States’ other arguments likewise fail.

ARGUMENT

I. The Final Rule is consistent with the ACA.

The States’ policy disagreements with the Final Rule, however fervent, do not change the legal reality that Congress did not mandate contraception in health plans. The ACA never used the term “contraception” in reference to preventive care, even though express references to contraception exist elsewhere in the ACA. *Compare* 42 U.S.C. § 300gg-13(a)(4) (“preventive care and screenings”) *with* 42 U.S.C. § 713(b)(2)(A) (sexual education program required to cover “both abstinence and contraception”). The States concede that “the statute grants HRSA the discretion” to pick the services that must be covered. *Opp.* 2.

Consistent with other guidelines implementing Section 300gg-13(a)(3) and (a)(4), which frequently define “who” is eligible to receive a service with no cost-sharing, both administrations to implement the ACA included exemptions in the contraceptive mandate concerning “who” must provide services. Br. 13-14. Yet according to the States, “‘mammograms for women over 40’ is an example of *what* must be covered; it does not change the *who* in any way.” *Opp.* 2 n.1. This is

semantic quibbling. A 39-year-old woman who seeks a mammogram is not entitled to that service without cost-sharing. A 41-year-old woman is. And of course the exemption and “accommodation”—upon which the States’ entire RFRA defense depends—purport to address *who* will provide services. Br. 15-18. If the ACA forbids who-but-not-what distinctions, the States’ case collapses, as does every version of the contraceptive mandate ever embraced by HHS.¹

What the States might mean is that the Guidelines *can* decide that only a subset of employees are eligible for a service without cost-sharing, but that they would prefer those subset rules be guided only by medical and insurer cost-based considerations. But unfortunately for the States, nothing in the ACA requires the agencies to limit their considerations to factors like insurer profits, especially where other federal law requires them to take religious practice into account.

II. The Agencies are permitted to issue the Rule to comply with RFRA.

A. Religious employers are substantially burdened by the Mandate’s fines.

In a two-page footnote, the States protest vigorously that the prior Administration did not obtain the *Geneva College* decision on “incorrect facts,” arguing about whether the agencies’ position changed at oral argument or in supplemental briefing. Opp. 7-8 n.5. That argument is silent, however, on the point that matters most: whether the States *disagree* with the Obama Administration’s admission that “accommodation” coverage is actually “part of the same ‘plan’ as the coverage provided by the employer.” *Id.* The States’ arguments fail on at least two points.

First, the States cannot—and indeed do not even try to—deny that accommodation coverage comes from the employer’s health plan, Br. 21-23; that a touted *benefit* of the “accommodation” system was precisely that women would *not* have two separate plans, Br. 22; or that the coverage depends on issuance of a plan instrument under the employer’s plan, *id.*, see Suppl. Br. for Resp’ts, *Zubik v. Burwell*, 136 S. Ct. 1557 (2016) (No. 14-1418), 2016 WL 1445915, at *17 (“There is *no*

¹ Although the States profess confusion, Opp. 3, the Little Sisters’ position on the legality of the religious exemption is clear. The 2011 religious exemption the States want to restore runs afoul of the First Amendment’s prohibition against discriminating among religious institutions because it is too narrow. Br. 37. Both the First Amendment and RFRA require the government to eliminate preferences among religious organizational structures that interfere with the internal affairs of religious groups, particularly where so many other avenues exist to serve the States’ claimed interest. Br. 25-26. It is therefore illegal for this Court to revive that version of the Rule.

mechanism for requiring TPAs to provide separate contraceptive coverage *without a plan instrument; self-insured employers could not opt out of the contraceptive-coverage requirement by simply informing their TPAs that they do not want to provide coverage for contraceptives.*”) (emphasis added).² Finally, the States fail to dispute the Little Sisters’ factual assertions that the Mandate requires them to take actions that violate their beliefs. *See* Dkt. 224-1 at 17-21 (“The States are without information to confirm or deny the specific factual allegations related to Little Sisters of the Poor.”).

Second, having failed to dispute the substantive accuracy of the prior Administration’s concessions, the States nowhere explain how the conceded facts can be reconciled with the facts as understood by the *Geneva College* panel, which erroneously thought the “accommodation” coverage was “totally disconnected” and “separate and apart from” the religious employers and their plans. *See Geneva Coll. v. Sebelius*, 778 F.3d 422, 439, 442 (3d Cir. 2015), *vacated and remanded by Zubik v. Burwell*, 136 S. Ct. 1557 (2016); *see also* Br. 21. And the States provide no explanation for why *Hobby Lobby* does not then fully control the substantial burden analysis, particularly now that the States admit the “accommodation” forces the Little Sisters to take actions that violate their religion. Dkt. 224-1 at 17-21.

Nor do the States substantively respond to *DeOtte*. *DeOtte* explains that the government’s representation that contraceptive coverage occurs within the employer’s plan “lends credibility to . . . the ‘plans as vehicles’ argument” that had been dismissed by the Fifth and Third Circuits upon adopting the government’s explanation of how the accommodation worked. Order at 14, *DeOtte v. Azar*, No. 4:18-cv-00825 (N.D. Tex. June 5, 2019), Dkt. 76.³ Ignoring *DeOtte*, the States stick to their story that it is hard to believe that “eight circuits got the question so wrong.” Opp. 8-9. But they offer no explanation for why the Supreme Court would have vacated the circuit court

² The States’ accusation of a “false[] assert[ion]” about *Zubik*’s recognition of the government’s changing view, Opp. 8 n.5, is thus doubly wrong. The *Zubik* statement did not confine itself to the supplemental briefs. And per the language above, the Government’s supplemental brief *did* further clarify—following pointed oral argument questions, Br. 23—that the accommodation requires actual employer and plan involvement rather than an “opt out” by “simply” raising an objection. Br. 31.

³ The States say the Little Sisters have “not pointed to any specific earlier statements from the government contradicting” the “same plan” admission. Opp. 8 n.5. *But see* Br. 21.

opinions if they were so obviously correct, nor why the Court would have noted the “gravity of the dispute.” 136 S. Ct. at 1560. Nor do they substantively engage with the dozens of courts that got the answer *right*—both before and after *Zubik*. Instead, the States snipe at the injunctions from footnotes. Opp. 6 n.3, 26-27 n. 21.

The States first suggest that some injunctions should not influence the agencies because they were unopposed. Opp. 6 n.3. But courts have an independent Article III obligation to discern whether a genuine case or controversy exists and weigh the merits before entering relief. “[W]hatever the Parties’ positions, it is for the Court to say whether Plaintiffs prevail.” Order at 11, *DeOtte v. Azar*, No. 4:18-cv-00825. That is why, for example, a district court “must first determine . . . whether the moving party has shown itself to be entitled to judgment as a matter of law” before granting summary judgment, even when no opposition has been filed. *Anchorage Assocs. v. Virgin Islands Bd. of Tax Review*, 922 F.2d 168, 175 (3d Cir. 1990). There is no suggestion here that district courts have been derelict in their constitutional duties; nor do the States ever explain what the agencies or their lawyers were supposed to do once they realized they could not in good faith assert the affirmative defense of strict scrutiny.

Second, the States complain that the Little Sisters did not explain sufficiently which injunctions were relevant to the agencies’ decisions, Opp. 26-27 n.21. While a case need not be live to be persuasive to the agencies in their decision-making process, there were numerous live injunctions in nonprofit cases not among the *Zubik* appeals at the time the IFRs were issued; injunctions that were *opposed by the government*.⁴ Beyond these, nine more injunctions were in effect upon the *Zubik* vacatur. See, e.g., *E. Tex. Baptist Univ. v. Sebelius*, 988 F. Supp. 2d 743 (S.D. Tex. 2013). All of these injunctions were contested and were live at the time of the IFRs. The States offer no theory by which the agencies were free to ignore them. In any event, the States’ persistent focus on the exact weight of authority also ignores *Real Alternatives*’ holding making clear that even were the federal government not obligated to issue the Final Rule, it is permitted to. “Even when

⁴ See, e.g., *Ave Maria Univ. v. Burwell*, 63 F. Supp. 3d 1363 (M.D. Fla. 2014); *Dobson v. Sebelius*, 38 F. Supp. 3d 1245 (D. Colo. 2014); *Brandt v. Burwell*, 43 F. Supp. 3d 462 (W.D. Pa. 2014); *La. Coll. v. Sebelius*, 38 F. Supp. 3d 766 (W.D. La. Aug. 13, 2014).

noninterference is not strictly required, the Government has discretion to grant certain religious accommodations subject to constitutional limitations.” *Real Alternatives, Inc. v. Sec’y, HHS*, 867 F.3d 338, 352 (3d Cir. 2017); *see also Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 728-30 (2014) (“RFRA surely allows” “modification of an existing program”). Certainly, *Zubik*’s invitation to develop a new “approach going forward” without a merits ruling demonstrates consensus that a court order is not required. 136 S. Ct. at 1560. The States make no effort to reconcile their argument with these controlling precedents.

B. The Government cannot satisfy strict scrutiny.

In a brief page of argument, the States assert that it has been “largely unquestioned” that the government has a compelling interest in achieving “full and equal” contraceptive coverage through the insurance plans of objecting religious employers. Opp. 9.

But the States provide no authority for the proposition that they can carry the federal government’s statutory burden on an affirmative defense the federal government is not asserting. *See* Br. 24 (citing RFRA’s text allocating strict scrutiny burden to federal government). Moreover, the States have not really attempted to meet the burden of proving that providing contraceptive access constitutes a compelling governmental interest. Opp. 9-10. It of course does not, as indicated by the States’ own lack of felt compulsion to mandate “full and equal” contraceptive access, *id.*, and the federal government’s failure to do so until 2011. *See* J.A. 3565 (Pennsylvania); 3569 (New Jersey).

In addition, the States fail to understand the difference between assuming a compelling interest in ensuring access to contraception and proving a compelling interest in providing access *via the Little Sisters’ plan*. The distinction is important, because as the agencies noted, the existing exemptions to the Mandate do enough “appreciable damage” to access via an employer’s plan to make clear that the kind of coverage the accommodation achieves was never treated as an interest “of the highest order.” *Church of Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 546-47 (internal quotations marks and citation omitted); *see* Br. 24-25 (noting the Mandate’s exemptions were justified in *Zubik* by reference to non-seamless alternative means of

contraceptive access). These include the religious employer exemption—which the States now take pains to avoid taking a position on—and the grandfathering and small employer exemptions.

The States’ failure to respond to evidence of less restrictive means to their goal of “‘full and equal’ access” is fatal. Opp. 9. That evidence includes government concessions of less restrictive means, Br. 7, a host of alternatives presented to the federal government (which the States fail to dispute), Dkt. 224-1 ¶¶ 65-67, and the States’ programs themselves, Br. 26. Those means function with or without the new Title X regulation. Br. 25, Opp. 10 n.6.⁵ Having chosen not to respond, the States have thus waived any contrary arguments.

III. The Final Rule is not arbitrary and capricious or procedurally invalid.

The above arguments demonstrate that the States’ arbitrary and capricious arguments—delving even into the details of the regulatory impact estimates—are misplaced. The thrust of the Final Rule is fundamentally that the prior accommodation triggered, and failed, RFRA’s strict scrutiny analysis. Whether most comments opposed the rules, Opp. 21, and whether the States have better assessed the benefits of contraception than the agencies, Opp. 18, does not bear on the Final Rule’s necessity. The agencies recognized: (1) the accommodation’s use of religious employers’ health plans meant that the “previous accommodation process did not actually accommodate the objections of many entities”; and (2) that being made to choose between “significant penalties” and involvement with contraceptive coverage “inconsistent with their religious observance or practice” was the “substantial burden identified by the Supreme Court in *Hobby Lobby*.” 83 Fed. Reg. 57,536, 57,544-46 (Nov. 15, 2018). Because there was a RFRA violation that required remediation, the agencies had a duty to act. That duty created good cause to act, and any error is harmless because “the outcome of the administrative proceedings” could not be changed by better

⁵ The Ninth Circuit has granted *en banc* review of the stay of the injunction of the new Title X regulations, but allowed the stay (and therefore the regulation) to remain in effect. Order, *California v. Azar*, No. 19-15974 (9th Cir. July 11, 2019), available at http://cdn.ca9.uscourts.gov/datastore/opinions/2019/07/11/19-15974_ebo.pdf.

or earlier consideration of comments. *See Green Island Power Auth. v. FERC*, 577 F.3d 148, 165 (2d Cir. 2009).⁶

IV. The Religious Exemption Rule violates no other law.

None of the States' scattershot objections shows that the Final Rule contravenes other laws.

Establishment Clause. The States continue to assert that religious exemptions are forbidden by the Establishment Clause. This is an especially silly claim given that the Supreme Court recently upheld a large Latin cross on public land in a 7-2 decision. *See Am. Legion v. Am. Humanist Ass'n*, No. 17-1717, 2019 WL 2527471 (U.S. June 20, 2019). If a large Latin cross does not establish religion, surely a religious exemption for nuns cannot either. But even before *American Legion*, the Supreme Court upheld and applied laws like RFRA and RLUIPA that benefit religion by relieving government burdens, as the "government acts with [a] proper purpose" when it "lift[s] a regulation that burdens the exercise of religion." *Corp. of Presiding Bishop v. Amos*, 483 U.S. 327, 338 (1987). *Amos* distinguishes direct government imposition of a burden on a third party from issues that arise when the government merely removes a burden the government itself had imposed on religious groups. Br. 24.⁷ *Hobby Lobby* in turn clarifies that, because almost every religious exemption can be framed as imposing a third-party harm, those harms are considered under the compelling interest test, not as an Establishment-Clause exception to RFRA. 573 U.S. at 731-32.

Equal Protection Clause, Title VII, and Section 1557. The States still have no authority for the proposition that an exception to a rule with a sex-based classification is itself a sex-based classification where that exception is offered without regard to sex. Again, the Little Sisters would object to providing male sterilization in their health care plans, but the Mandate only requires such coverage for women. Assuming every injunction against the Mandate is not judicial defiance of

⁶ The States assert in a footnote that the Little Sisters do not dispute a host of arguments related to arbitrary-and-capricious review. Opp. 16 n.11. While the Little Sisters have focused on the agencies' RFRA duties, their initial motion contests many arguments to which the States refer, including whether there is a compelling interest in seamless access to contraception and whether serious reliance interests are endangered by the Final Rule. *See, e.g.*, Br. 30-32.

⁷ The States' attempt to distinguish *Amos* by claiming that "the exemption here is not necessary to prevent significant government interference with a religious institution's ability to carry out its religious mission." Opp. 15 n.10. But the Little Sisters and many other religious employers have shown that the Mandate's fines would be devastating to their mission. *See* J.A. 2294.

the Equal Protection Clause, this argument is without merit. And the sex-based classification is the “only” ACA provision the government addressed, Opp. 11, because it is the only one that produced dozens of lawsuits, multiple Supreme Court losses, and dozens of live injunctions.

The States’ Title VII and Section 1557 challenges fail for similar reasons. If taken seriously, they would invalidate *every* exemption from a state or federal contraceptive mandate—the grandfathering exception in the federal Mandate, the religious exemption in the New Jersey mandate, and so forth. *But see Doe v. Bolton*, 410 U.S. 179, 198 (1973) (religious exemption from abortion provision was “appropriate protection”). Particularly when the States offer no contrary authority to the case law rejecting analogous challenges, this Court should refrain from adopting such broad reasoning. *See In re Union Pac. R.R. Emp’t Practices Litig.*, 479 F.3d 936, 942 (8th Cir. 2007) (Title VII does not mandate contraceptive coverage); *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 690 (N.D. Tex. 2016) (concluding Section 1557 incorporates the broad religious exemption scheme of Title IX).

Section 1554. The States’ argument that an exemption for religious employers “creates . . . unreasonable barriers to the ability of individuals to obtain appropriate medical care” is confused. Opp. 10 (quoting 42 U.S.C. § 18114(1)). They say “the Rules reflect the Agencies’ choice to allow certain plan sponsors to *deny* women the benefits of the Mandate—rather than a decision ‘not to impose’ a mandate in the first place.” Opp. 11. But as the States note, HRSA—a division of HHS—was the body that “concluded that contraception” should be covered, creating the mandate. *Id.*; Opp. 2 (“the statute grants HRSA the discretion”). If the States are trying to suggest that a mandate may be limited initially without running afoul of Section 1554, but can never be retracted once extended, they do not provide any authority for reading Section 1554 as a one-way ratchet.

Regardless, the argument that narrowing a policy intended to promote contraception access constitutes an “unreasonable barrier” runs headlong into the Supreme Court’s decision in *Rust v. Sullivan*, 500 U.S. 173 (1991). There, the Court made clear that “Congress’ refusal to fund abortion counseling and advocacy,” even in a policy change, “leaves a pregnant woman with the same choices as if the Government had chosen not to fund family-planning services at all,” and therefore

“do not impermissibly burden” access to abortion. *Rust*, 500 U.S. at 201-02. Here, the policy change does not reduce access from the status quo. If the government can choose not to provide services, surely the government can allow nuns to choose not to provide services, just like Pennsylvania allows all employers not to provide contraception for any reason. And here, of course, the federal government is actually trying to provide those services directly. *See* 84 Fed. Reg. 7714, 7739 (Mar. 4, 2019).

V. The States lack standing to challenge the Final Rule.

While the States disagree (without much explanation) with the injunction in *DeOtte*, they do not persuasively explain why it does not foreclose their standing to bring a challenge to the Final Rules.⁸ An injunction is no less in force for being subject to appeal. And while the States say briefly that the injunction does not reach religious universities’ student plans, it does not point to any objecting university, in either state, that could not be protected by another injunction. Even Geneva College eventually received a permanent injunction on remand. *See* Permanent Injunction, *Geneva Coll. v. Sebelius*, No. 2:12-cv-00207 (W.D. Pa. July 5, 2018), Dkt. 153. The States do not explain how this Court can provide any effective relief, given that the federal government is barred from enforcing the prior rules.

The States’ most remarkable claim is that because “state officials enforce the mandate with respect to insurance providers,” the Final Rule is more expansive than *DeOtte*. Opp. 29. It appears that the States are saying that even though *DeOtte* issued an injunction and declaratory judgment that the Mandate violates the Religious Freedom Restoration Act, the States could still enforce the federal Mandate themselves. The States provide no authority for this claim, and it is implausible that states could lawfully enforce federal regulations duly found unlawful by an Article III court. Indeed, if States have this newly-announced power, then presumably every *other* state in the

⁸ The States’ estoppel argument against the agencies, Opp. 4-5, is another reminder that the States have no way of getting effective relief from this Court. In the scenario that the ACA is unconstitutional, the States cannot receive an order from this Court requiring the government to enforce the Mandate under the ACA but not the Final Rule. If the ACA is invalid, the States cannot receive the relief they seek.

country remains free to this day to ignore this Court's rulings and apply the IFR and Final Rule because Pennsylvania mistakenly sued only the federal government and not other States.

CONCLUSION

This Court should grant summary judgment in favor of the Defendants and deny the States' summary judgment motion. In the alternative, Defendant-Intervenors respectfully request that, if the Court accepts the States' arguments, the Court invalidate the regulations implementing the Mandate prior to October 13, 2017 pursuant to the States' arguments.

Dated: July 12, 2019

Respectfully submitted,

/s/ Mark Rienzi

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was electronically filed with the Clerk of the Court for the United States District Court for the Eastern District of Pennsylvania using the CM/ECF system, and that service will be effectuated through the CM/ECF system.

Dated: July 12, 2019

/s/ Mark Rienzi
Mark Rienzi

**UNITED STATES DISTRICT COURT
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LITTLE SISTERS OF THE POOR SAINTS
PETER AND PAUL HOME,

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Civil No. 2:17-CV-04540-WB

**DEFENDANT-INTERVENOR'S
REPLY TO PLAINTIFFS'
OPPOSITION TO DEFENDANT-
INTERVENOR'S STATEMENT OF
UNDISPUTED MATERIAL FACTS**

Defendant-Intervenor Little Sisters of the Poor Saints Peter and Paul Home respectfully replies as follows to the Plaintiff States' response to the Little Sisters' Statement of Undisputed Material Facts. Pursuant to the Court's Policies and Procedures for Civil Cases, Policy V.C.3, this Reply provides a response to factual disputes only, and give no reply where the States have made legal arguments, such as where the states have asserted that a proposed fact is a legal conclusion, irrelevant, or undisputed. The absence of a reply in those circumstances is not a concession of anything other than the Little Sisters' stated fact.

To differentiate text, Plaintiff States' responses are rendered in italics and follow the initial question where applicable. Replies follow responses in indented paragraphs.

General Responses

***Response:** The States object generally to Intervenor's own characterizations of the statutes and regulations to the extent that these characterizations differ from the text of these documents. The statutes and regulations speak for themselves. The States also object generally to Intervenor's use of the words "abortion," "abortion-inducing," and "abortifacients" when referring to methods of contraception covered by the HRSA Guidelines. "Every FDA-approved contraceptive acts before implantation, does not interfere with a pregnancy, and is not effective after a fertilized egg has implanted successfully in the uterus." E.g., J.A. 647.*

REPLY: Nothing in this response or citation contests that some contraceptives may function "by preventing attachment (implantation) to the womb (uterus)" of an already-fertilized egg, as indicated in the Food and Drug Administration's Birth Control Guide. J.A. 2349 (copper IUD); 2362 (levonorgestrel); J.A. 2363 (ulipristal acetate). Nothing in this response or citation contests that the Little Sisters "affirm that life begins at conception," J.A. 2289, or explains why abortion cannot reasonably be defined to include acts "caus[ing] the demise of a post-fertilization embryo," J.A. 18-19 (Final Rule noting dispute in language). The States' cited authority in the Joint Appendix itself cites to an

amici curiae brief in *Hobby Lobby* as authority for its quoted statement. That brief is available online and simply defines as “pre-pregnancy” all time prior to implantation. Brief of Amici Curiae Physicians for Reproductive Health, et al. at 18, *Sebelius v. Hobby Lobby Stores, Inc.*, 571 U.S. 1067 (2013) (No. 13-354), available at <http://sblog.s3.amazonaws.com/wp-content/uploads/2013/10/13-354-BRIEF-OF-AMICI-CURIAE-PHYSICIANS-FOR-REPRODUCTIVE-HEALTH-et-al....pdf>. Further

response is given to specific objections below.

Specific Responses

I. The Federal Mandate and Its Regulatory History

1. Congress has never enacted a federal statute listing contraceptives as part of required health insurance. J.A. 99.

Response: Paragraph 1 states a legal conclusion to which no response is required.

2. Congress does not require that cost-free access to all FDA-approved contraceptives be provided by small employers. 26 U.S.C. § 4980H(c)(2)(A).

Response: Paragraph 2 states a legal conclusion to which no response is required.

3. Congress does not require that cost-free access to all FDA-approved contraceptives be provided in grandfathered health plans. J.A. 306, 2176.

Response: Paragraph 3 states a legal conclusion to which no response is required.

4. Congress does not require cost-free access to all FDA-approved contraceptives in public-sector plans such as Medicare, Medicaid, and Tricare. J.A. 383 (“preventive services requirements . . . affect only private plans”).

Response: Paragraph 4 states a legal conclusion to which no response is required.

5. The Affordable Care Act requires certain employers to offer “health insurance coverage” that includes “preventive care and screenings” for women without “any cost sharing requirements.” 42 U.S.C. § 300gg-13(a)(4); 26 U.S.C. § 9815; 29 U.S.C. § 1185d.

Response: Paragraph 5 states a legal conclusion to which no response is required.

6. Under the Affordable Care Act, the penalty for offering a plan that excludes coverage for even one of the FDA-approved contraceptive methods is \$100 per day for each affected individual. 26 U.S.C. § 4980D(a)-(b).

Response: Paragraph 6 states a legal conclusion to which no response is required.

7. If an employer larger than 50 employees fails to offer a plan at all, the employer owes \$2,000 per year for each of its full-time employees. 26 U.S.C. § 4980H(a), (c)(1).

Response: Paragraph 7 states a legal conclusion to which no response is required.

8. “Family planning” was mentioned only in passing during Senate floor debates concerning the Women’s Health Amendment, while many senators went into considerable detail about cost and access to mammograms, pap smears, post-partum depression, domestic violence, heart disease, and diabetes. J.A. 2377-79, 2422-26, 2435-38.

Response: Disputed. In fact, multiples Senators discussed the need to include family planning in coverage of preventive services during debate on the Women’s Health Amendment. Ex. 151.

REPLY: This response does not controvert the asserted fact. The record reflects that the phrase “family planning” is used three times in the debate and only as part of longer lists. See, e.g., J.A. 2423 (“[g]eneral yearly well-women visits would be covered; pelvic examinations, family planning services, pregnancy, and post partum depression screenings, chlamydia screenings for all women over 25. . . .”); J.A. 2526; J.A. 2529. The record reflects that the benefits and costs of other services were discussed at length. See, e.g., J.A. 2525 (heart disease screening; breast cancer screening).

9. The preventive services mandate was first implemented in an interim-final rule on July 19, 2010 (“First IFR”), which stated that the Health Resources and Services Administration

(“HRSA”) would produce “comprehensive guidelines” for women’s preventive services. J.A. 564.

***Response:** Disputed that the referenced interim final rules “implemented” the preventive services mandate, which was enacted by Congress. The regulation otherwise speaks for itself.*

REPLY: The States’ dispute is a legal conclusion to which no reply is required. To the extent a reply is required, the response is disputed to the extent that the States suggest Congress mandated any particular service. “Congress did not specify any particular additional preventive care and screenings with respect to women that HRSA could or should include in its Guidelines, nor did Congress indicate whether the Guidelines should include contraception and sterilization,” J.A. 99; *see* States’ Opposition to Motions for Summary Judgment at 2 (“the statute grants HRSA the discretion to identify *what* preventive services must be covered”).

10. Nothing in the Affordable Care Act requires HRSA to include contraceptives in its comprehensive guidelines. J.A. 306.

***Response:** Paragraph 10 states a legal conclusion to which no response is required.*

11. This First IFR was enacted without prior notice of rulemaking or opportunity for prior comment as it came into effect on the day that comments were due. J.A. 562, 566.

***Response:** Disputed. The regulation referenced was published July 19, 2010, and went into effect September 17, 2010.*

REPLY: This response is consistent with the asserted fact. The regulation came into effect on September 17, 2010, and comments were due on or before September 17, 2010—the same day. J.A. 562. The agencies “determined that it [was] impracticable and contrary to the public interest to engage in full notice and comment rulemaking” before implementing the first IFR. J.A. 566.

12. The First IFR did not mention family planning as a “preventive service,” instead listing “immunizations . . . blood pressure and cholesterol screening, diabetes screening for hypertensive patients, various cancer and sexually transmitted infection screenings, genetic testing for the BRCA gene, adolescent depression screening, lead testing, autism testing, and oral health screening and counseling related to aspirin use, tobacco cessation, and obesity.” J.A. 567.

Response: Undisputed that the quoted language appears in the regulation. J.A. 567. The regulation further stated, “The Department of HHS is developing these guidelines [for preventive services for women] and expects to issue them no later than August 1, 2011.” J.A. 564.

13. HRSA commissioned the Institute of Medicine (“IOM”) to “review what preventive services are necessary for women’s health and well-being and should be considered in the development of comprehensive guidelines for preventive services for women.” The charge to the IOM does not include any discussion of coverage issues. J.A. 326-27.

Response: Undisputed that the cited page contains the quoted text. The further characterization of the IOM report is disputed. The report speaks for itself. *Id.*

REPLY: Nothing in the States’ response controverts the asserted fact. The charge to the committee speaks for itself. J.A. 326-27.

14. The IOM Report argues that greater use of contraception will lower rates of unintended pregnancy, but the Mandate is about increasing access to contraception. Studies have shown that there are “many and varied reasons why women choose not to use contraception, most of which have nothing to do with cost.” J.A. 2220, 2249-51.

Response: Disputed. Paragraph 14 cites a single law review article, not a research study. To the extent a further response is required, the States dispute Intervenor’s contention that the mandate does not facilitate greater use of contraception. The States

also dispute that the IOM report focused on use at the exclusion of access. Women can have different and multiple reasons for not using contraception, and “cost sharing can be a significant barrier to access to contraception.” J.A. 242 (citation omitted). This is particularly true for the most effective forms of contraception, where effectiveness is measured “by studying the rate of failure (i.e., having an unintended pregnancy) in the first year of use.” J.A. 430-31. “Cost barriers to use of the most effective contraceptive methods are important because long-acting, reversible contraceptive methods and sterilization have high up-front costs (Trussell et al., 2009).” J.A. 433. “[M]ultiple studies have demonstrated that when financial and logistical barriers are removed, women overwhelmingly select the most effective forms of contraception.” J.A. 648 (citations omitted).

REPLY: The response is consistent with the second asserted fact, agreeing that “Women can have different and multiple reasons for not using contraception.” As to the characterization of the IOM Report, the IOM Report’s substantive analysis section is titled “Effective Interventions” and the Report prefaces its citation of anticipated cost-savings as “beyond the scope of the committee’s consideration.” J.A. 429-32. To the extent the States are suggesting record citation should exclude documents that summarize studies, the States extensively cite in their Responses and their own Statement to agency comments and reports that summarize footnoted studies. In any case, the States offer no response to the existence and summary of the particular studies relied upon in the cited article. *See, e.g.,* William D. Mosher & Jo Jones, *Use of Contraception in the United States: 1982-2008*, 23 *Vital & Health Statistics*, Aug. 2010, at 14, available at https://www.cdc.gov/nchs/data/series/sr_23/sr23_029.pdf; Catherine Stevens-Simon et al., *Why Pregnant Adolescents Say They Did Not Use Contraceptives*

Prior to Conception, 19 J. Adolescent Health 48 (1996), available at [https://www.jahonline.org/article/1054-139X\(95\)00281-V/pdf](https://www.jahonline.org/article/1054-139X(95)00281-V/pdf).

15. In reports by the CDC, Guttmacher, and other organizations, the cost of birth control did not appear as an explanation for low rates of contraceptive use. Instead, the studies found that factors such as mistaken assumptions about infertility, worries about the side effects of birth control, and indifference or ambivalence to pregnancy were the main drivers behind women not using contraceptives. J.A. 2249.

Response: Disputed. Paragraph 15 cites a single law review article, not a research study. The States lack information as to whether the law review article accurately summarizes the underlying studies, and therefore dispute that the underlying studies demonstrate that cost is not an explanation for low rates of contraceptive use. To the extent a further response is required, the States dispute that cost is not a barrier to the use of contraception. See Response 14.

REPLY: The response does not provide information contradicting the summary. The cited law review article accurately summarizes studies which conclude that the primary reasons for nonuse of contraceptives are unrelated to access or cost. See Reply 14 (same studies). The Final Rule likewise notes the existence of a Guttmacher study stating that “income is not associated with use of most other methods [besides male sterilization and withdrawal] obtained through health care settings” with the use of many contraceptive methods. J.A. 13 (alteration in original).

16. Some studies show that the overall proportion of unintended pregnancies does not correlate to changes in contraceptive use. J.A. 2227.

Response: Disputed. Paragraph 16 cites a single law review article, not a research study. The States lack information as to whether the law review article accurately

summarizes the underlying studies, and therefore dispute that the underlying studies demonstrate that there is no correlation between changes in contraceptive use and unintended pregnancies. To the extent a further response is required, the States dispute that contraception does not prevent unintended pregnancy. E.g., J.A. 649 (citations omitted), 799-800, 807, 1329-30 (citation omitted).

REPLY: The response does not provide information suggesting the article inaccurately summarizes the cited studies; the citations are to rulemaking comments that purport to summarize other studies. The law review article accurately summarizes the relevant studies; *see* Reply 14 (same studies).

17. The CDC reports that 12% of women using contraception will become pregnant in a given year. This figure essentially stayed the same between 1995 and 2010. J.A. 2220.

Response: *Disputed. Paragraph 17 cites a single law review article, not a research study. The States lack information as to whether the law review article accurately summarizes the underlying CDC report, and therefore dispute that the underlying report supports the inference that contraception has no impact on unintended pregnancies. To the extent a further response is required, the States dispute the relevance of Paragraph 17. No method of contraception is 100 percent effective, some methods of contraception are less effective than others, and all methods of contraception must be used both consistently and correctly to maximize effectiveness. J.A. 431.*

REPLY: The response does not provide information suggesting the article inaccurately summarized the cited studies, and its factual assertions are consistent with the facts asserted. The cited article accurately quotes the cited Mosher & Jones study; *see* Reply 14. Paragraph 17 is material and relevant to, *inter alia*, the States' claims as to whether the marginal interest in contraceptive access served by denying

a religious exemption to the Contraceptive Mandate is a compelling interest.

18. Other studies have shown that the increase in contraception access and use is possibly connected to increasing rates of STIs, as access to contraception generally leads to more sex with more partners. J.A. 2236-38.

***Response:** Disputed. Paragraph 18 cites a single law review article, not a research study. In addition, the States lack information about whether the law review article accurately summarizes the underlying studies, and therefore dispute that the underlying studies demonstrate that an increase in contraception access and use is causally connected to an increasing rate of STIs or to more sex with more partners.*

REPLY: The response does not provide information suggesting the article inaccurately summarized the cited studies. The article accurately summarizes the studies it cites as noting a “possible relationship,” J.A. 2236-37; *see* Reply 14 (addressing use of summaries). The cited studies speak for themselves. *See* Christine Durrance, *The Effects of Increased Access to Emergency Contraception on Sexually Transmitted Disease and Abortion Rates*, 51 *Economic Inquiry* 1682, Dec. 2012, at 1694, available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2261572; Charles S. Morrison et al., *Hormonal Contraceptive Use, Cervical Ectopy, and the Acquisition of Cervical Infections*, 31 *Sexually Transmitted Diseases* 561, Sept. 2004, at 566, available at <https://www.ncbi.nlm.nih.gov/pubmed/15480119>.

19. Studies have shown that there are a variety of potential harms to women’s health from the use of contraceptives, including ties to cancer. J.A. 2238-40.

***Response:** Disputed. Paragraph 19 cites a single law review article, not a research study. The States lack information as to whether the law review article accurately summarizes the underlying studies, and therefore dispute that the underlying studies*

demonstrate a variety of potential harms to women’s health from the use of contraceptives. To the extent a further response is required, the States dispute the categorical treatment of all contraceptive methods. All methods of contraception—like all medications—have side effects and can pose risks to some users. E.g., J.A. 651. But all methods of contraception also have benefits that must be weighed against these risks. Id. This is why “patients and physicians, not politicians, should determine the right contraceptive for a patients’ health care needs.” Id.

REPLY: The response does not provide information suggesting the article inaccurately summarized the cited studies, and its statement that “[a]ll methods of contraception—like all medications—have side effects and can pose risks to some users” is consistent with the summarized assertions of the studies. The cited article accurately summarizes the studies and publications hyperlinked within, J.A. 2240-41; *see* Reply 14 (addressing use of summaries). The cited studies speak for themselves. For example, the World Health Organization publication cited refers to estrogen-progesterone oral contraceptives as “known carcinogens.” *Carcinogenicity of Combined Hormonal Contraceptives and Combined Menopausal Treatment*, World Health Org., 2005, available at https://www.who.int/reproductivehealth/topics/ageing/cocs_hrt_statement.pdf. Estrogen-progesterone oral contraceptives are FDA-approved contraceptive methods covered by the Mandate. J.A. 2352. The final two sentences of the response are legal conclusions and require no response.

20. The World Health Organization has classified oral contraceptives as carcinogens. JA 17-18, 2240.

Response: *Disputed. Paragraph 20 cites a single law review article, not a research study. The States lack information as to whether the law review article and the Final*

Religious Exemption Rule accurately summarize the underlying WHO Report. To the extent a further response is required, the States dispute the implication that oral contraceptives are categorically unsafe. The American Cancer Society recognizes that oral contraceptives “confer[s] a protective effect against cancer in the endometrium and ovary.” J.A. 3392. The FDA has also approved oral contraceptives as safe and effective. J.A. 2352-53. That oral contraceptives may pose risks to some women reinforces the importance of women making individualized decisions in consultation with their doctors, not their employers.

REPLY: The response does not provide information suggesting the article or Final Rule inaccurately summarized the cited classification, and its additional factual assertions are not inconsistent with the classification. The article and Final Rule accurately summarize the classification, J.A. 2240; *see* Reply 14 (addressing use of summaries). The cited report, discussed further in Reply 19, speaks for itself.

21. FDA-approved contraceptive methods required by the Mandate include “emergency contraception.” The FDA’s Birth Control Guide notes that some emergency contraceptives may work by preventing implantation of a fertilized egg in the uterus. J.A. 2361-63.

Response: Disputed to the extent it inaccurately summarizes the cited document. The FDA’s Birth Control Guide states that emergency contraception “works mainly by stopping the release of an egg from the ovary.” J.A. 2362.

REPLY: The response does not point to any information contradicting the cited document, and its citation for how emergency contraception “mainly” works is consistent with the fact offered.

22. The list of FDA-approved contraceptive methods endorsed by the IOM Report includes methods that can interfere with a human embryo before implantation. J.A. 2362-63.

Response: Disputed. The FDA does not use the words “human embryo.” Id.

REPLY: Undisputed that the Birth Control Guide does not use the words “human embryo” in the cited pages. The States do not dispute that the Guide states that some contraceptive methods work in the stated way. J.A. 2362-63. The Guide states, for example: “[Emergency Contraception] may also work by preventing fertilization of an egg (the uniting of sperm with the egg) or by preventing attachment (implantation) to the womb (uterus).” J.A. 2362.

23. According to the FDA’s own publication, each of the 18 methods it has approved can have side effects and other health risks. At least forty potential side effects are mentioned throughout the document, ranging from irritation and tiredness all the way to “severe infection[s]” or ectopic pregnancies, as well as some “Less Common Risks” such as heart attack or stroke. J.A. Ex. 147.

***Response:** Disputed to the extent it inaccurately summarizes the cited document. The States dispute the implication that the existence of side effects categorically renders all methods of contraception unsafe for all women. See also Response 19.*

REPLY: The States do not point to evidence contradicting the stated fact. Neither the fact nor the cited Guide describe “all methods of contraception as unsafe for all women.”

23a. 16 of the 18 approved methods provide no protection against STIs. Two provide a “reduced risk” of STIs. J.A. Ex. 147.

***Response:** Paragraph 23.a is not material to this litigation. The States also the implication that contraception is not safe or beneficial. See Response 19.*

REPLY: Paragraph 23.a is material and relevant to, *inter alia*, the States’ claims as to whether the marginal interest in contraceptive access served by denying a religious exemption to the Contraceptive Mandate is a compelling interest. Any dispute as to the import of the asserted fact is a legal conclusion to which no

response is required.

23b. The FDA's publication claims that one method of emergency contraception it has approved has an 87.5% chance of preventing a pregnancy but admits that "other studies have resulted in lower pregnancy prevention rates." J.A. 2362.

***Response:** Disputed to the extent Paragraph 23.b suggests that access to emergency contraception has no benefit for women. Not all methods of contraception are equally effective. See Response 17.*

REPLY: The response is consistent with the fact as asserted. Any dispute as to the implications of the asserted fact is a legal conclusion and no response is required.

23c. The FDA states the other method of emergency contraception it has approved has only a 60-66% chance of preventing a pregnancy. J.A. 2363.

***Response:** Disputed to the extent Paragraph 23.c suggests that access to emergency contraception has no benefit for women. Not all methods of contraception are equally effective. See Response 17.*

REPLY: The response is consistent with the fact as asserted. Any dispute as to the implications of the asserted fact is a legal conclusion to which no response is required.

24. Thirteen days after the IOM recommendations were issued, the HRSA issued guidelines on its website. The HRSA guidelines included "[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures." J.A. 310-11.

***Response:** Undisputed.*

25. HRSA's inclusion of contraceptive coverage in the preventive services guidelines is posted on its website and has never been subject to notice-and-comment rulemaking. J.A. 101.

***Response:** Undisputed that the HRSA Guidelines are posted on the agencies' website. The remainder of the paragraph states a legal conclusion to which no response is*

required.

26. The same day that the HRSA guidelines were posted on its website, HHS promulgated its Second IFR, effective immediately, once again without prior notice or opportunity for public comment. J.A. 304.

Response: *Undisputed.*

27. The Second IFR stated that it “contain[ed] amendments” to the First IFR, in particular recognizing that Congress’s grant of authority to HRSA to develop “guidelines” included the authority to consider the impact of the Mandate on religious objectors. J.A. 304, 306.

Response: *Disputed that Congress granted HRSA authority to consider the impact of the contraceptive mandate on religious objectors. 42 U.S.C. § 300gg-13(a)(4).*

REPLY: The response does not rebut that the Second IFR made the representations expressed in the stated fact. J.A. 304, 306. Disputes with the legal conclusions reached by the Second IFR are themselves legal conclusions and require no response.

28. The Mandate has many gaps, including that employers with fewer than 50 employees need not provide insurance coverage at all. 26 U.S.C. § 4980H(c)(2)(A).

Response: *Paragraph 28 states a legal conclusion to which no response is required.*

29. Approximately a fifth of large employers are exempt through ACA’s exception for “grandfathered health plans.” J.A. 306, 2176.

Response: *Disputed. Paragraph 29 mischaracterizes the record. J.A. 2176 states that in 2017, “23% of firms offering health benefits offer at least one grandfathered health plan.” This does not mean that a fifth of large employers are exempt.*

REPLY: The response does not dispute that the “requirements to cover recommended preventative services without any cost-sharing do not apply to grandfathered health plans.” J.A. 306. It follows that “23% of firms offering health

benefits offer at least one” health plan to which the requirements do not apply. J.A. 2176.

30. The Second IFR acknowledged HRSA’s discretion to exempt certain religious employers from the guidelines, but it defined religious employer narrowly, ultimately excluding nonprofits like the Little Sisters of the Poor, who serve people of all faiths. J.A. 306.

***Response:** Disputed to the extent Paragraph 30 asserts that HRSA has authority to exempt certain religious employers from the Guidelines.*

REPLY: The response does not dispute the asserted fact as stated, which relates to what the Second IFR acknowledged and defined. Any disputation of the legal conclusions reached by the Second IFR is itself a legal conclusion and no response is required.

31. The Agencies received “over 200,000” comments, including many comments that explained the need for broader religious exemptions, but the Second IFR was finalized “without change.” J.A. 299-00, 298.

***Response:** Disputed to the extent Paragraph 31 implies that the Agencies did not adequately respond to these comments.*

REPLY: The response does not dispute the asserted fact as stated. Any dispute of the legal ramifications of the asserted fact is a legal conclusion and no response is required.

32. The Agencies then published an Advance Notice of Proposed Rulemaking and a Notice of Proposed Rulemaking, which were later adopted into a final rule making further changes to the Mandate. J.A. 290, 269-70, 239.

***Response:** Disputed. The ANPRM, NPRM, and final rule addressed how the contraceptive mandate would be implemented through changes to the church exemption and creation of the accommodation. They did not make changes to the*

conclusion that contraceptive methods and counseling are preventive services for women and therefore must be provided by covered plans without cost-sharing, pursuant to the Women’s Health Amendment. E.g., J.A. 241.

REPLY: The response does not dispute, and is consistent with, the facts that the ANPRM and NPRM were adopted into a Final Rule, which announced “changes” to the Mandate. The response’s statement about their legal significance and the scope of the Women’s Health Amendment is a legal conclusion to which no response is required. To the extent that a response is required, disputed that all “preventive services for women” must be covered without cost-sharing under the Women’s Health Amendment. *See* 42 U.S.C. § 300gg-13(4) (“such additional preventive care and screenings . . . as provided for in comprehensive guidelines”); J.A. 306 (“certain” preventive services).

33. The Agencies received over 600,000 comments in response to the ANPRM and NPRM. J.A. 240, 272.

Response: *Undisputed.*

34. The Agencies amended the definition of a religious employer, but continued to limit that definition to churches and the “exclusively religious” activities of religious orders. J.A. 243.

Response: *Paragraph 34 states a legal conclusion to which no response is required.*

35. The Agencies also adopted a mechanism—termed an “accommodation”—by which religious employers could offer the objected-to coverage on their health plans by executing a self-certification and delivering it to the organization’s insurer or third-party administrator (TPA). Self-certification would trigger the insurer’s or TPA’s obligation to provide payments for contraceptive services. J.A. 243.

Response: *Disputed to the extent Paragraph 35 implies that the accommodation does*

not accommodate the objections of certain religious employers for the purposes of the Religious Freedom Restoration Act. Paragraph 35 otherwise states a legal conclusion to which no response is required.

REPLY: Any disputation of the legal consequences of the mechanism for claims under the Religious Freedom Restoration Act is a legal conclusion to which no response is required.

36. The regulations stated that: “plan participants and beneficiaries (and their health care providers) do not have to have two separate health insurance policies (that is, the group health insurance policy and the individual contraceptive coverage policy).” J.A. 245.

***Response:** Paragraph 36 states a legal conclusion to which no response is required. The regulations speak for themselves. To the extent a response is required, the States note that the prior two sentences provide necessary context: “As the payments at issue derive solely from a federal regulatory requirement, not a health insurance policy, they do not implicate issues such as issuer licensing and product approval requirements under state law, and they minimize cost and administrative complexity for issuers. At the same time, because the payments for contraceptive services are not a group health plan benefit under this approach, this policy ensures that eligible organizations and their plans do not contract, arrange, pay, or refer for contraceptive coverage, and that such coverage is expressly excluded from their group health insurance policies.” J.A. 245.*

REPLY: The language of the Final Rule is undisputed, and speaks for itself. To the extent that the additional quoted language is offered as an accurate description of the regulation’s functioning, the additional quoted language represents a legal conclusion to which no reply is required.

37. On EBSA Form 700, the self-certification form, there is a “Notice to Third Party Administrators of Self-Insured Health Plans,” which states that the form “constitutes notice to the third party administrator that . . . [t]he obligations of the third party administrator are set forth in 26 C.F.R. § 54.9815-2713A, 29 C.F.R. § 2510.3-16, and 29 C.F.R. § 2590.715-2713A,” and that “[t]his certification is an instrument under which the plan is operated.” J.A. 1971. It is these regulations that require that “the third party administrator will provide or arrange payments for” the abortifacient drugs and devices. 26 C.F.R. § 54.9815-2713A; 29 C.F.R. § 2510.3-16; 29 C.F.R. § 2590.715-2713A. J.A. 1971-72.

***Response:** Undisputed that EBSA Form 700 contains the quoted language. Disputed that third party administrators will provide or arrangement payment for abortifacient drugs and devices. The second sentence of Paragraph 37 is a conclusion of law to which no response is required.*

REPLY: As explained at greater length in the reply to the general response at p. 1-2 , some contraceptives may function “by preventing attachment (implantation) to the womb (uterus)” of a developing human organism, J.A. 2362-63, thereby “caus[ing] its demise” and qualifying as abortifacient under one common use of the term. J.A. 18-19.

38. The first two IFRs did not address the concerns of many religious organizations and many filed lawsuits under the Religious Freedom Restoration Act seeking relief. J.A. Ex. 138.

***Response:** Disputed to the extent that Paragraph 38 suggests the contraceptive mandate, as implemented with a church exemption and accommodation, violated the Religious Freedom Restoration Act.*

REPLY: The response does not dispute the fact as written. Any disputations about the legal merits of the filed lawsuits are legal conclusions and require no response.

39. In July 2013, one of the organizations that had sued for relief, Wheaton College, received an emergency injunction from the Supreme Court that protected it from the penalties in the Mandate. J.A. 221; *Wheaton College v. Burwell*, 134 S. Ct. 2806 (2014).

Response: Disputed. The Supreme Court's injunction protected Wheaton College only if it "informs the Secretary of Health and Human Services in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services." Wheaton Coll. v. Burwell, 134 S. Ct. 2806, 2807 (2014).

REPLY: The information provided in the response is consistent with the asserted fact that Wheaton College received an emergency injunction that protected it from penalties.

40. Following that injunction and "in light of the Supreme Court's interim order" in the Wheaton case, the agencies published a third IFR, again without preceding notice or comment. J.A. 228.

Response: Undisputed.

41. The agencies issued the IFR despite the fact that the Supreme Court in Wheaton stated that its order "'should not be construed as an expression of the Court's views on the merits' of Wheaton College's challenge to the accommodations." J.A. 221.

Response: Undisputed that the Supreme Court's Wheaton decision contains the quoted language.

42. The Third IFR amended the Mandate to allow a religious objector to "notify HHS in writing of its religious objection" rather than notifying its insurer or third-party administrator. J.A. 230.

Response: Disputed to the extent Paragraph 42 suggests this regulation was the "Third IFR." Paragraph 42 otherwise states a legal conclusion to which no response is

required. The regulation speaks for itself.

REPLY: To the extent that the response’s dispute of the word “Third” is a dispute as to which interim final rules are relevant to this litigation, it is a legal conclusion to which no response is required. To the extent a response is required, the Federal Register publication here cited was described as “Action: Interim final rules” and was effective on August 27, 2014, J.A. 228. It was preceded by a Federal Register publication described as “Action: Interim final rules with request for comments” that was effective on September 17, 2010, J.A. 562, and another Federal Register publication described as “Action: Interim final rules with request for comments” that was effective on August 1, 2011, J.A. 304. Further, the States note the preceding Paragraph 40 as undisputed, which uses the phrase “third IFR” to describe the same regulation. The States do not suggest another way to number the IFRs issued before the IFRs that led to this lawsuit.

43. The Third IFR was ultimately finalized on July 14, 2015. J.A. 188-89.

Response: *Undisputed.*

44. The final rule implementing the Third IFR stated: “the third party administrators and health insurance issuers already paying for other medical and pharmacy services on behalf of the women seeking the contraceptive services are better placed to provide seamless coverage of the contraceptive services, than are other providers that may not be in the insurance coverage network, and that lack the coverage administration infrastructure to verify the identity of women in accommodated health plans and provide formatted claims data for government reimbursement.” J.A. 198-99.

Response: *Paragraph 44 states a legal conclusion to which no response is required. The regulation speaks for itself.*

45. The Third IFR did not accommodate the religious beliefs of the Little Sisters and other religious objectors, leading to more litigation. J.A. 1951.

Response: Paragraph 45 contains a legal conclusion to which no response is required. To the extent a response is required, the States dispute that the accommodation, as amended on July 14, 2015, did not accommodate the religious beliefs of the Little Sisters and other religious objectors for the purposes of the Religious Freedom Restoration Act.

REPLY: The States' disputation of whether the Little Sisters' beliefs were accommodated is itself a legal conclusion and requires no response. The States do not offer a dispute of the Little Sisters' religious beliefs.

II. The Challenges to the Mandate and the Resulting Injunctions

Response [to] Paragraphs 46-49, 51-54, 56, 58-60: The States are without information to confirm or deny the specific factual allegations related to Little Sisters of the Poor. The States further object to the use of the words "abortion," "abortion-inducing," and "abortifacient" when referring to methods of contraception covered by the HRSA Guidelines.

REPLY: The response does not provide any reason to doubt the factual allegations made in the Declaration of Mother Superior Marie Vincente regarding the Little Sisters of the Poor, J.A. 2284-2343 (Declaration and Exhibit). These facts are therefore undisputed. The Little Sisters note that their beliefs as to impermissible actions are also supported by the record evidence of specific Catholic teachings on health care. J.A. 2323, 2326. The dispute as to the definition of abortion is addressed in the reply to the general response at p. 1-2.

46. The Little Sisters of the Poor is an international Roman Catholic organization of nuns that has provided care to the elderly poor—of any race, sex, or religion—for over 175 years. J.A. 2285.
47. The Saints Peter and Paul Home of the Little Sisters of the Poor in Pittsburgh is a Pennsylvania non-profit corporation that qualifies as a tax-exempt organization under section 501(c)(3) of the Internal Revenue Code of 1986. The Pittsburgh home is under the direct authority of Mother Superior Marie Vincente. J.A. 2286.
48. The Little Sisters home in Pittsburgh employs around 67 full-time employees. J.A. 2286.
49. The Little Sisters Pittsburgh have adopted the Christian Brothers Employee Benefit Trust to provide medical benefits coverage for their employees. Christian Brothers Trust is a Catholic entity designed to serve the Catholic Church and related faith-based entities. The Little Sisters chose to use the Christian Brothers Trust for their health benefits because it shares and is administered in accordance with the Little Sisters’ religious beliefs and provides benefits accordingly. J.A. 2286-87.
50. As an employer participating in the Christian Brothers Employee Benefit Trust Plan, the Little Sisters Pittsburgh Home is currently protected by an injunction from enforcement of the Mandate. Order, *Little Sisters of the Poor v. Azar*, No. 1:13-cv-02611 (D. Colo. May 29, 2018), Dkt. 82.

Response: Undisputed.

51. The Little Sisters homes are not under the civil legal ownership and control of the dioceses in which they are located. Instead, the Little Sisters of the Poor own and control the homes themselves, through local corporations. J.A. 2286.
52. The Little Sisters’ homes are not directly funded by the dioceses in which they are located. They take responsibility for funding their own operations. J.A. 2286.

53. The Little Sisters follow all the teachings of the Catholic Church, including its teachings that abortion, contraception, sterilization, and cooperation with such acts are intrinsically immoral. J.A. 2288-89.
54. Catholic teachings also instruct the Little Sisters to provide their employees and their employees' families with adequate healthcare benefits. J.A. 2290-91.
55. The agencies' contraceptive mandate, as it existed before the Final Rules, requires the Little Sisters to participate in the provision of contraception, abortion, and sterilization to their employees via the use of their health plans, health plan information, and health plan infrastructure. J.A. 2291.

***Response:** Disputed. Prior to the Final Rules, the Little Sisters were free to take advantage of the accommodation. E.g., Ex. 10. The States dispute Paragraph 55 as mischaracterizing how the accommodation functions. E.g., J.A. 245. The States further dispute Paragraph 55 to the extent it implies that the accommodation substantially burdens the Little Sisters' religious beliefs in violation of the Religious Freedom Restoration Act.*

REPLY: The Little Sisters do not dispute that the accommodation was available to them. The Little Sisters do dispute that the regulations prior to the Interim Final Rules constituted an actual accommodation of their religious beliefs. J.A. 2291-2293. As to their objection to how the accommodation functions, the States cite without quotes to regulations implemented before the Third IFR. Those regulations speak for themselves. They also state: "plan participants and beneficiaries (and their health care providers) do not have to have two separate health insurance policies (that is, the group health insurance policy and the individual contraceptive coverage policy)." J.A. 245. Whether the accommodation constitutes a substantial burden is a conclusion of law to which no reply is required.

56. Because of their religious beliefs, the Little Sisters sincerely believe that they cannot:

- a. participate in the Mandate's program to promote and facilitate access to the use of sterilization, contraceptives, and abortion-inducing drugs and devices. J.A. 2291.
- b. provide health benefits to their employees and plan beneficiaries that will include or facilitate access to sterilization, contraceptives, and abortion-inducing drugs and devices. J.A. 2292.
- c. designate, authorize, or incentivize any third party to provide their employees or plan beneficiaries with access to sterilization, contraception, and abortion-inducing drugs and devices. J.A. 2292.
- d. sign, execute, deliver, or otherwise file documents with a third party or the government which could then be used to require, authorize, or incentivize a third party to provide their employees with access to sterilization, contraception, or abortion-inducing drugs. J.A. 2292.
- e. agree to refrain from speaking with a third party to ask or instruct it not to deliver contraceptives, sterilization, and abortifacients to their employees and plan beneficiaries in connection with the Little Sisters' health plan. J.A. 2292.
- f. create or facilitate a provider-insured relationship, the sole purpose of which would be to provide contraceptives, sterilization, and abortifacients in connection with the Little Sisters' health plans. J.A. 2292.
- g. create, maintain, support, or facilitate health insurance plans, information, and infrastructure that would be used to provide contraceptives, sterilization, and abortifacients to their employees and plan beneficiaries. J.A. 2292-93.
- h. take any action that would require, authorize, or incentivize Christian Brothers Trust or Christian Brothers Services to violate their own Catholic religious beliefs. J.A. 2293.

- i. provide employee health benefits that include access to contraception. J.A. 2292.
 - j. Execute Form 700 to use the “accommodation.” J.A. 2292.
 - k. Provide the notice to HHS to use the “accommodation.” J.A. 2291.
57. The “accommodation” cannot result in the Little Sisters’ employees receiving contraceptive coverage “seamlessly” with the Little Sisters’ plan unless the Little Sisters take actions that violate their sincerely held religious beliefs. J.A. 2295, 2297.

***Response:** Disputed. Paragraph 57 mischaracterizes how the accommodation functions. E.g., J.A. 245. The States further dispute Paragraph 57 as implying that the accommodation substantially burdens the Little Sisters’ religious beliefs in violation of the Religious Freedom Restoration Act.*

REPLY: The States do not dispute the Little Sisters’ religious beliefs. See Paragraph 56. Without quotation, the States cite regulations from 2013. Those regulations speak for themselves. The regulations also state: “plan participants and beneficiaries (and their health care providers) do not have to have two separate health insurance policies (that is, the group health insurance policy and the individual contraceptive coverage policy).” J.A. 245. Whether the regulations constitute a substantial burden on the Little Sisters’ beliefs is a legal conclusion.

58. Even the so-called accommodation would require the Little Sisters to act as a necessary link in the government’s plan to provide contraceptive measures to their employees, in violation of their beliefs. J.A. 2295.

***Response:** Disputed. Paragraph 58 mischaracterizes how the accommodation functions. E.g., J.A. 245. The States further dispute Paragraph 58 as implying that the accommodation substantially burdens the Little Sisters’ religious beliefs in violation of the Religious Freedom Restoration Act.*

REPLY: See reply to Paragraph 57. J.A. 2291-93.

59. Without an exemption, the Mandate would require the Little Sisters Pittsburgh home to pay millions of dollars in fines each year for not providing contraceptive coverage. J.A. 2294.
60. The Little Sisters cannot in good conscience avoid the fines by choosing not to provide health benefits at all, but even if they did, they would face annual fines of approximately \$134,000 for dropping benefits altogether. J.A. 2294-95.
61. The Mandate imposes enormous pressure on the Little Sisters to participate in activities prohibited by their sincerely held religious beliefs. J.A. 2295.

***Response:** Disputed to the extent that Paragraph 61 suggests the contraceptive mandate, as implemented with the church exemption and accommodation, substantially burdens the Little Sisters' religious beliefs in violation of the Religious Freedom Restoration Act.*

REPLY: The States do not dispute the asserted fact that the Little Sisters are pressured by the Mandate. Nor do the States dispute that the actions required by the Mandate are “activities prohibited by [the Little Sisters’] sincerely held religious beliefs.” Whether the regulations constitute a substantial burden on the Little Sisters’ beliefs is a legal conclusion.

62. Lawsuits by the Little Sisters and others have resulted in injunctions from federal courts across the country. J.A. 15, 103-04, 2593.

***Response:** To the extent Paragraph 62 refers to recently obtained permanent injunctions based on claims that the accommodation violates the Religious Freedom Restoration Act, the States dispute the relevance of these decisions. In every case the Agencies have failed to defend the accommodation and thus each injunction does not constitute a determination about the legality of the accommodation.*

REPLY: The States do not dispute the existence of injunctions that bind the

agencies. The States' conclusion that an injunction making factual and legal findings by an Article III Court "does not constitute a determination about the legality of the accommodation" is disputed and is a legal conclusion. The States do not define what they mean by "recently obtained" injunctions; it is denied that "[i]n every case" resulting in an injunction against the accommodation, the agencies have not defended the accommodation. *See* Little Sisters' Reply Supp. Summ. J. at 4.

63. After the Supreme Court issued an order in *Zubik v. Burwell*, the agencies issued a "Request for Information" in July 2016, to seek input on "whether there are modifications to the accommodation that would be available under current law and that could resolve the RFRA claims raised by organizations that object to the existing accommodation on religious grounds." J.A. 183.

Response: Disputed to the extent that Paragraph 63 mischaracterizes the full nature of the Agencies' request, which stressed the importance of "ensuring that women enrolled in the organizations' health plans have access to seamless coverage of the full range of Food and Drug Administration-approved contraceptives without cost sharing." J.A. 183.

REPLY: The text of the Request for Information is undisputed and speaks for itself. J.A. 183.

64. The Request for Information received over 54,000 public comments. J.A. 1806, 1844.

Response: Undisputed.

65. Included in those comments were suggestions for how to provide access to contraceptives for employees of religious and moral objectors that would not require the use of the employers' plans, including through willing doctors, pharmacies, or contraceptive-only plan. *See, e.g.,* J.A. 3645-67.

Response: Paragraph 65 is not material or relevant to this litigation.

REPLY: Paragraph 65 is relevant to, *inter alia*, whether the Mandate is the least restrictive means by which the government can provide access to contraceptives.

The States do not dispute the facts in this paragraph.

66. At least one of those comments explained a Missouri law that accomplished such an arrangement in 2001 with an available contraceptive-only plan. J.A. 3650-67.

Response: *Paragraph 66 is not material or relevant to this litigation.*

REPLY: Paragraph 66 is relevant to, *inter alia*, whether the Mandate is the least restrictive means by which the government can provide access to contraceptives.

The States do not dispute the facts in this paragraph.

67. Another comment suggested ways that pharmacies could be used to seamlessly provide contraceptives to women without the use of an employer's plan. J.A. 3645-49.

Response: *Paragraph 67 is not material or relevant to this litigation.*

REPLY: See reply to Paragraph 65. The States do not dispute the facts in this paragraph.

68. The agencies concluded, in a set of FAQs published only on the Department of Labor's website 11 days before inauguration day, that they were unable to modify the accommodation because "no feasible approach has been identified at this time" that would allow them to do so in a way that respected both the agencies' goals and the religious objectors' concerns. J.A. 169, 172.

Response: *Disputed. Paragraph 68 mischaracterizes what the Agencies stated in the 2017 FAQs: "[T]he Departments continue to believe that the existing accommodation regulations are consistent with RFRA for two independent reasons. First, as eight of the nine courts of appeals to consider the issue have held, by virtue of objecting employers' ability to avail themselves of the accommodation, the contraceptive-coverage requirement does not substantially burden their exercise of religion. Second,*

as some of those courts have also held, the accommodation is the least restrictive means of furthering the government's compelling interest in ensuring that women receive full and equal health coverage, including contraceptive coverage.” J.A. 172.

REPLY: The States offer no facts to dispute the factual assertions in this paragraph. The text of the FAQs is undisputed and speaks for itself. The language the States quote is on J.A. 172-73. Any interpretation of the text is a legal conclusion to which no response is required.

69. The agencies never explained why using pharmacies, willing doctors, or contraceptive only plans would not be feasible solutions. J.A. 172.

Response: *Paragraph 69 is not material or relevant to this litigation.*

REPLY: Paragraph 69 is relevant to, *inter alia*, whether the Mandate is the least restrictive means by which the government can provide access to contraceptives.

The States do not dispute the facts in this paragraph.

70. On October 13, 2017, the agencies issued the Fourth IFR. J.A. 98.

Response: *Undisputed.*

71. The Fourth IFR stated the following: “Consistent with . . . the Government’s desire to resolve the pending litigation and prevent future litigation from similar plaintiffs, the Departments have concluded that it is appropriate to reexamine the exemption and accommodation scheme currently in place for the Mandate.” J.A. 105.

Response: *It is undisputed that the quoted language appears in the regulation.*

72. The Fourth IFR stated that: “we have concluded that requiring such compliance through the Mandate or accommodation has constituted a substantial burden on the religious exercise of many . . . and . . . we conclude requiring such compliance did not serve a compelling interest and was not the least restrictive means of serving a compelling interest. . . .” J.A. 112.

Response: *It is undisputed that the quoted language appears in the regulation.*

73. The Fourth IFR stated that: “Good cause exists to issue the expanded exemption in these interim final rules in order to cure such violations [of RFRA] (whether among litigants or among similarly situated parties that have not litigated), to help settle or resolve cases, and to ensure, moving forward, that our regulations are consistent with any approach we have taken in resolving certain litigation matters.” J.A. 120.

Response: *It is undisputed that the quoted language appears in the regulation.*

74. The Fourth IFR provided that the Mandate would not be enforced against “employers that object to coverage of all or a subset of contraceptives or sterilization and related patient education and counseling based on sincerely held religious beliefs.” J.A. 114.

Response: *It is undisputed that the quoted language appears in the regulation.*

75. The IFRs left the Mandate and the accommodation in place as they applied to other employers who do not have religious or moral objections. J.A. 98.

Response: *Paragraph 75 states a legal conclusion to which no response is required. The regulation speaks for itself.*

76. There was a 60-day comment period for the IFRs. J.A. 98.

Response: *Undisputed.*

77. Pennsylvania did not provide comments to the federal government during any of the comment periods related to the contraceptive mandate from 2010-2016.

Response: *Paragraph 77 is not material or relevant to this litigation.*

REPLY: Paragraph 77 is relevant to Pennsylvania’s interest in the enforcement of the Mandate. The States do not dispute the facts in this paragraph.

78. New Jersey did not provide comments to the federal government during any of the comment periods related to the contraceptive mandate from 2010-2016.

Response: *Paragraph 78 is not material or relevant to this litigation.*

REPLY: Paragraph 78 is relevant to New Jersey's interest in the enforcement of the Mandate. The States do not dispute the facts in this paragraph.

79. Pennsylvania, for the first time in six notice and comment periods, filed comments on the Fourth IFR on December 5, 2017. J.A. 1384-1392.

***Response:** Undisputed that Pennsylvania filed comments on December 5, 2017, opposing the Religious and Moral Exemption IFRs. Disputed that whether Pennsylvania filed comments previously is relevant or material to this litigation.*

REPLY: Paragraph 79 is relevant to Pennsylvania's interest in the enforcement of the Mandate. The States do not dispute the facts in this paragraph.

80. New Jersey did not join that comment. J.A. 1384-1392.

***Response:** Disputed that whether New Jersey filed comments previously is material or relevant to this litigation.*

REPLY: Paragraph 80 is undisputed. J.A. 1384-1392. Paragraph 80 is relevant to New Jersey's interest in enforcement of the Mandate.

81. After receiving comments and reviewing them over a period of several months, the agencies finalized the IFRs in final rules that took effect on January 14, 2019, 60 days after they were published in the Federal Register. J.A. 1, 5.

***Response:** Disputed. The final rules did not take effect on January 14, 2019, because they were enjoined by this Court. The States also dispute Paragraph 81 to the extent it implies that the Agencies complied with the notice and comment requirements of the APA.*

REPLY: Undisputed that this Court's injunction prevented the Final Rules from being enforced by the defendant agencies. The States do not dispute the rest of the factual statements in Paragraph 81. Whether the agencies complied with the notice and comment requirements of the APA is a legal conclusion.

82. The Commonwealth of Pennsylvania does not have a contraceptive mandate of its own. J.A. 3565.

***Response:** Paragraph 82 states a legal conclusion to which no response is required. Pennsylvania has taken several steps to provide its citizens with access to healthcare, including contraceptive care. J.A. 3563-66; 3703-08.*

REPLY: The States do not dispute the asserted fact. The Little Sisters do not dispute that Pennsylvania has taken steps, other than a contraceptive mandate, to provide its citizens with access to contraceptives. J.A. 3704-08.

83. New Jersey's state contraceptive mandate has a religious exemption that is broader than the agencies' initial religious exemption. J.A. 3569.

***Response:** Paragraph 83 states a legal conclusion to which no response is required. The States dispute that New Jersey's state contraceptive mandate has a broader religious exemption. J.A. 3568-69.*

REPLY: New Jersey's definition of religious employers that qualify for exemptions includes religious schools. J.A. 3569. The federal definition under the initial religious exemption did not include this category. J.A. 243. The cited declaration includes this quote: "church-affiliated schools eligible for New Jersey's religious exemption, [FN3] would no longer have an obligation to provide any contraceptive coverage." Footnote 3 states: "Churches and associations and conventions of churches have been exempted from the ACA's Contraceptive Care Mandate since 2011. *See* 76 Fed. Reg. 46621-01 (Aug. 3, 2011). However, unlike Defendants' broad new religious exemption, the 2011 exemption was not applicable to most church-affiliated schools." J.A. 3570 & n.3.

84. Between 1995 and 2010, 28 states instituted mandates similar to the HHS Mandate, requiring private health insurance plans to cover various forms of contraception. J.A. 2261.

***Response:** Disputed. Paragraph 84 cites to a law review article that itself cites an article from 1994 as its sole source of authority for the above claim. J.A. 2261.*

REPLY: Nothing in the States' response controverts the asserted fact. Additionally, the cited law review article also cites to the National Conference of State Legislators as authority for the claim in Paragraph 84. *Insurance Coverage for Contraception Laws*, National Conference of State Legislatures (Feb. 2012), <http://www.ncsl.org/research/health/insurance-coverage-for-contraception-state-laws.aspx>; J.A. 2261, 2270.

85. At least one study has shown that those contraception mandates had little impact on unintended pregnancy rates or abortion rates. J.A. 2282-83.

***Response:** Disputed. Paragraph 85 cites a law review article, not a research study. The States further dispute that the mandate has not had an impact on unintended pregnancy rates or abortion rates.*

REPLY: The States cite no evidence for their dispute about the Mandate's impact on unintended pregnancy and abortion rates. The characterization of the citation in Paragraph 85 as merely a "law review article" is misleading. The article in question is a "time series cross-sectional analysis of state level public health data," J.A. 2259, which uses regression analysis to draw conclusions from data taken from CDC and Guttmacher reports. J.A. 2267-69.

86. The States have not provided evidence of a single individual who would lose coverage as a result of the Final Rules. J.A. 1801, 1851.

***Response:** Disputed. The States have provided evidence that women in Pennsylvania and New Jersey are likely to lose contraceptive coverage as a result of the Final Rules. ECF No. 162.*

REPLY: The response does not dispute that the States have never pointed to an

actual “single individual” who would lose coverage, only asserting that it is “likely” that some women will lose contraceptive coverage. The pleading cited names employers “that either litigated against the Mandate or had taken advantage of the Accommodation,” ECF No. 162 at 5, but does not specify which, if any, would deny contraceptive coverage to a qualified individual as a result of the Final Rule.

87. Pennsylvania has never enacted a statute or issued a regulation to ensure that all of its female citizens of reproductive age receive seamless access to cost-free contraceptive coverage.

***Response:** Disputed. Pennsylvania has taken several steps to provide its citizens with access to healthcare, including contraceptive care. J.A. 3563-66; 3703-08.*

REPLY: The response does not dispute Paragraph 87, which only states that Pennsylvania has never “enacted a statute or issued a regulation” to achieve the specific compelling interest asserted for the Mandate in this case. The response’s cited material specifies that Pennsylvania “does not have a ‘contraceptive parity’ statute” that would require “coverage for any Food and Drug Administration-approved contraceptive.” J.A. 3565.

88. New Jersey has never enacted a statute or issued a regulation to ensure that all of its female citizens of reproductive age receive seamless access to cost-free contraceptive coverage.

***Response:** Disputed. Paragraph 88 is misleading. The Gennace Declaration states that “New Jersey law requires employers who offer fully-insured plans to provide coverage for expenses incurred in the purchase of prescription female contraceptives to the same extent as any other outpatient prescription drug under the policy.” J.A. 3568-69.*

REPLY: The response is consistent with Paragraph 88, and confirms that the law is limited to those citizens covered by fully-insured plans. The Gennace Declaration further clarifies that “the New Jersey mandate does not require insurers to cover

women’s contraceptive services without cost sharing” and that the mandate in any event only extends to “those methods which are obtained via prescription (not those that are available over the counter or through an inpatient or out-patient procedure).” J.A. 3569.

Dated: July 12, 2019

Respectfully submitted,

/s/ Mark Rienzi

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the forgoing document was electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

Dated: July 12, 2019

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